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Attorney Docket No. P32151

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Craig et al.		April 23, 1999
Serial No.:			Group Art Unit No.:
Filed:	April 23, 1999		Examiner:
For:	Novel Compound		

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT UNDER 37 C.F.R. §1.115

Sir:

Applicants respectfully request that the following amendments and remarks be made of record prior to examination of the above-cited application.

In the Claims:

Please cancel claims 1 to 39 and add claims 40-75 as follows:

40. Paroxetine methanesulfonate.

41. A compound according to claim 40 in non-crystalline form.

42. A compound according to claim 40 in crystalline form.

43. A compound according to claim 42 having *inter alia* the following characteristic IR peaks: 1603, 1513, 1194, 1045, 946, 830, 776, 601, 554, and 539 ± 4 cm-1.; and/or the following characteristic XRD peaks: 8.3, 10.5, 15.6, 16.3, 17.7, 18.2, 19.8, 20.4, 21.5, 22.0, 22.4, 23.8, 24.4, 25.0, 25.3, 25.8, 26.6, 30.0, 30.2, and 31.6 ±0.2 degrees 2 theta.

44. A process for the preparation of a compound as claimed in claim 40 by precipitation from a solution of a paroxetine methanesulfonate, spray drying or freeze drying

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a solution of a paroxetine methanesulfonate, evaporating a solution of a paroxetine methanesulfonate to a glass, or by vacuum drying of oils of a paroxetine methanesulfonate, or solidification of melts of a paroxetine methanesulfonate.

45. A process for the preparation of a compound as claimed in claim 42 selected from the group consisting of crystallization or re-crystallization from a solution of a paroxetine methanesulfonate in a solvent.

46. A process according to claim 44 in which the solution, oil or melt of a paroxetine methanesulfonate is prepared by chemical modification of a precursor paroxetine methanesulfonate salt.

47. A process according to claim 44 in which the solution, oil or melt of a paroxetine methanesulfonate is prepared by treating paroxetine free base or a labile derivative thereof with methanesulfonic acid or a labile derivative thereof.

48. A process according to claim 47 in which the paroxetine free base or a labile derivative thereof is provided *in situ* from a preceding reaction step in which the paroxetine free base, or a labile derivative thereof, has been formed.

49. A process according to claim 47 in which the labile derivative of paroxetine free base is an organic acid salt thereof and the labile derivative of methanesulfonic acid is an ammonium or amine salt thereof.

50. A process according to claim 44 in which the solution, oil or melt of a paroxetine methanesulfonate is prepared by deprotecting an acid-labile protected paroxetine precursor with methanesulfonic acid.

51. A process according to claim 45 in which the solution comprises an aromatic hydrocarbon, water, an alcohol, an ester, a ketone, an amide, a heterocyclic amine, a halogenated hydrocarbon, a nitrile, an ether or a mixture thereof.

52. A process according to claim 51 in which the solvent comprises toluene, an alcohol, an ester, a ketone, a halogenated hydrocarbon, a nitrile, or an ether, optionally in admixture with water, an ether, or a lower alcohol, or mixtures thereof.

53. A process according to claim 45 in which the solvent forms an azeotrope with water and prior to isolation of the product water is removed by azeotropic distillation.

54. A process according to claim 45 in which the crystallisation is promoted by inclusion of an anti-solvent to the solvent.

55. A process according to claim 54 in which the anti-solvent is an ether or hexane.

56. A process according to claim 45 in which the crystallisation is conducted at elevated temperature followed by controlled cooling.

57. A process according to claim 45 in which crystallisation is induced by the addition of a seed crystal.

58. A process according to claim 45 in which crystallisation is conducted without the addition of a seed crystal.

59. A pharmaceutical composition comprising a compound according to claim 40 and a pharmaceutically acceptable carrier.

60. A composition according to claim 59 in which the carrier comprises a disintegrant.

61. A composition according to claim 59 in which the carrier comprises a binder.

62. A composition according to claim 59 in which the carrier comprises a colouring agent.

63. A composition according to claim 59 in which the carrier comprises a flavouring agent.

64. A composition according to claim 59 in which the carrier comprises a preservative.

65. A composition according to claim 59 adapted for oral administration.

66. A composition according to claim 65 which is a tablet or capsule.

67. A composition according to claim 66 which is a modified oval shaped tablet.

68. A composition according to claim 59 comprising 1 to 200mg of active ingredient, calculated on a free base basis.

69. A method for treating and/or preventing any one or more of the Disorders by administering an effective and/or prophylactic amount of a compound according to claims 40 to a sufferer in need thereof.

70. A 1:1 solvate of paroxetine methanesulfonate with acetonitrile.

71. A process for preparing paroxetine hydrochloride by converting paroxetine methanesulfonate.

72. A pack containing a pharmaceutical composition according to claim 59.

73. A compound according to claim 42 substantially as described in Example 2.

74. A process according to claim 73 substantially as described in Examples 51.

75. A composition according to claim 59 substantially as described in Example 54.

Serial No.: Not Yet Assig
Group Art Unit No.: Not Yet Assigned

REMARKS

The amendment presented above has been introduced in order to correct and eliminate multiple dependencies and comply with the proper U.S. claim format.

Respectfully submitted,

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